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Kalginate ® 510(K) SUMMARY

1. Name and Address of Applicant

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2. Name of the Device

Classification Name - Dental Impression Material.

Common Name - Alginate Impression Material.

Trade Name - Kalginate ® Impression Material.

3. Legally Marketed Device for Substantial Equivalence Determination

The Company's Kalginate ® Impression Material, a preamendment device.

4. Description of the Device

Kalginate ® is a powdered material, that is mixed with water and placed in the patients oral cavity. It contains alginate, an essential gel forming material, that reacts with water to form an elastic material suitable for making impressions of the patients teeth and oral tissues.

5. Intended use of the device

The intended use of Kalginate ®, a Dental Alginate Impression Material, is to obtain impressions of the patient's teeth and oral tissues.

6. Material/Technological Characteristics

The color pigment material for the Company's Kalginate ® Impression Material, Valencia Orange, is changed to Red Pigment # 38. A specification sheet and a Material Safety Data Sheet are enclosed.

7. Performance data

Performance

Accelerated shelf life testing was conducted on a batch of the new Kalginate ® Impression Material. The batch was mixed and processed using Research and Development equipment. Test samples from the batch were aged for 3 months at 23° and 40° C. The elevated temperature represents a 2 year shelf life. A summary of the tests and the results is discussed in Appendix 4. The results show no stability difference between the new and old Kalginate ® Impression Material formulations.

Biocompatibility

Test results from a cheek Pouch Mucosal Irritation Histopathology Study indicates that the Kalginate ® formulation with the Red Pigment #38 is non-irritating to the cheek pouch mucosa of hamsters.